

**Claim Objections**

Claims 3 and 20 are objected to by the Examiner because in claim 3 "maltohexaose" is mistyped and in claim 20 "of" is typed instead of "higher than" after "an isoelectric point". Applicants have amended the claims as suggested by the Examiner. Applicants respectfully request reconsideration and withdrawal of the objection.

**Claim Rejections - 35 U.S.C. § 112, First Paragraph**

Claim 3 is rejected by the Examiner under 35 U.S.C. § 112, first paragraph, for lack of written description. Applicants respectfully traverse and request reconsideration and withdrawal of the rejection.

The Examiner asserts that claim 3 encompasses a great number of  $\alpha$ -amylases having unknown structures and possessing the requisite properties. The Examiner asserts that she was unable to locate adequate support in the Specification for such  $\alpha$ -amylases. Applicants note that on page 1, lines 21-22 it is shown that different sources for  $\alpha$ -amylase were contemplated. Additionally, on page 2, lines 10-22 other alkaline  $\alpha$ -amylases that show maximal

activity in the alkaline pH range are disclosed. Thus, the instant Specification provides adequate support for the  $\alpha$ -amylases recited in claim 3.

The Examiner asserts that there is no limitation on structural homology in claims 3, 20 and 21. As discussed above, the Specification discloses that different sources for  $\alpha$ -amylase were contemplated. Additionally, the Specification discloses other alkaline  $\alpha$ -amylases that show maximal activity in the alkaline pH range. Applicants have also added new claims 22-24 which are drawn to a DNA molecule encoding a protein exhibiting alkaline liquefying  $\alpha$ -amylase activity at a pH optimum of 8-9 comprising at least one of SEQ ID NO's 3-11 which are the PCR primers used in the instant invention. These claims disclose a limitation on structural homology.

Claims 3, 4, 15, 16, 20 and 21 are rejected for lack of enablement. Applicants respectfully traverse and request reconsideration and withdrawal of the rejection.

The Examiner asserts that one of skill in the art cannot predict *a priori* what changes can be made in a protein sequence and yet retain enzymatic activity. Applicants, however, assert that in the art of molecular

biology, such predictability is not necessary, as the standard approach is to make a library of changes and screen them for activity. Applicants note that the Specification discloses adequate screening assays. For example, on page 9, lines 1-11, a screening assay is disclosed for identifying target recombinant microorganisms. Additionally, on page 17, lines 20-24, an activity assay is recited which could be used by a person of ordinary skill in the art to screen for mutant a DNA molecule encoding a protein exhibiting alkaline liquefying  $\alpha$ -amylase activity. Thus, adequate description is provided in the Specification to enable one of ordinary skill in the art to make and/or use the invention commensurate in scope with the instant claims.

**Claim Rejections - 35 U.S.C. § 112, Second Paragraph**

Claim 2, with dependent claims 5-7 and 14, and claim 3 are rejected by the Examiner under 35 U.S.C. § 112, second paragraph, as being indefinite. Applicants respectfully request reconsideration and withdrawal of the rejection.

The Examiner asserts that claim 2 refers to SEQ ID NO: 1 where it appears that SEQ ID NO: 2 is intended. The Examiner further asserts that in claim 2, in the recitation of "functional fragment having  $\alpha$ -amylase activity",

"functional" is redundant. Applicants have amended the claims to comply with the requirements of 35 U.S.C. § 112, second paragraph.

The Examiner asserts that in claim 3, it is unclear what is the difference between "added" and "inserted". Applicants have amended claim 3 by deleting the word "added

**Claim Rejections - 35 U.S.C. § 102**

Claims 3, 4, 15 and 16 are rejected by the Examiner under 35 U.S.C. § 102 as being anticipated by Tsukamoto et al. or Yuuki et al. The Examiner asserts that the DNAs disclosed by Tsukamoto et al. and Yuuki et al. can be construed as DNAs encoding SEQ ID NO: 2 having substitutions, deletions and additions. Applicants respectfully request reconsideration and withdrawal of the rejection.

The instant invention is not anticipated by Tsukamoto et al. or Yuuki et al. because the  $\alpha$ -amylases of Tsukamoto et al. and Yuuki et al. have different enzymatic properties than the  $\alpha$ -amylases of the instant invention. Neither of the cited references disclose an  $\alpha$ -amylase whose pH optimum is 8-9. In this regard, claim 3 is amended to recite "A DNA molecule encoding a protein exhibiting alkaline liquefying  $\alpha$ -

amylase activity at a pH optimum of 8-9..." Support is found on page 11, lines 19-20. Therefore, the instant invention, as amended, is not anticipated by Tsukamoto et al. or Yuuki et al.

**Claim Rejections - 35 U.S.C. § 103**

Claims 3, 4, 15, 16, 20 and 21 are rejected as being obvious over Ara et al. in view of Tsukamoto et al. or Yuuki et al. The Examiner asserts that it would have been obvious to a person of ordinary skill in the art to follow the procedures taught by Tsukamoto et al. and Yuuki et al. in order to isolate a DNA encoding an alkaline liquefying  $\alpha$ -amylase from Bacillus sp. KSM-AP1378, as disclosed in Ara et al. Applicants respectfully traverse and request reconsideration and withdrawal of the rejection.

The instant invention is not obvious over Ara et al. in view of Tsukamoto et al. or Yuuki et al. It would not be predictable by one of skill in the art, upon reading the references cited by the Examiner, how to obtain an enzyme that would have a pH optimum of activity in the range of pH 8-9, in view of the prior teachings of sources of enzymes having pH optima in the range of pH 5 to 8. Prior to the instant invention, a liquefying amylase with a pH optimum

of 8-9 was unknown. Another unknown factor was which amino acid residues of the neutral liquefying amylase contribute to enhancement of the activity in the alkaline region. The Examiner has applied an "obvious to try" standard which the courts have ruled is not an appropriate test for determining obviousness under 35 U.S.C. § 103 (See Hybritech Inc. v. Monoclonal Antibodies, Inc., 231 USPQ 81 (CAFC 1986).; and Jones v. Hardy, 220 USPQ 1021 (CAFC 1984).) Obvious to try does not make an invention obvious. Therefore, the instant invention is not obvious over Ara et al. in view of Tsukamoto et al. or Yuuki et al.

#### **CONCLUSION**

As the above-presented amendments and remarks address and overcome all of the rejections presented by the Examiner, withdrawal of the rejections and allowance of the claims are respectfully requested.

Pursuant to 37 C.F.R. §§1.17 and 1.136(a), Applicants respectfully petition for a one (1) month extension of time for filing a response in connection with the present application and the required fee of \$110.00 is attached hereto.

If the Examiner has any questions concerning this application, he is requested to contact the undersigned, at

(703) 205-8000 in the Washington, D.C. area.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

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